

REMARKS

Prosecution

Applicants respectfully request reconsideration of the outstanding rejections in view of Applicants' instant claim amendments and the following Remarks.

Claim Amendments

Upon entry of the foregoing amendment, claims 1 and 10 are pending in the application. Claims 2-9 and 11-47 are canceled. Claims 1 and 10 are amended. Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed, *inter alia*, and in particular on page 1 lines 1-9; page 10 lines 5-8; page 11 lines 23-29; page 15 lines 13-17; page 17 lines 10-11; page 20 lines 9-26; and Figures 2-3. Applicants respectfully note that the limitations of claim 35, which were indicated as allowable in the Office Action, have been incorporated into claims 1 and 10. Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter.

Priority

Applicants respectfully note that certified copies of GB 9711214.8 and GB 9801990.4 were filed in the parent patent application U.S. Application No. 09/450,651 on February 4, 2000. Copies of the priority documents are enclosed for the Examiner's convenience.

Applicants respectfully request that the claim to foreign priority be acknowledged.

Election/Restrictions

Applicants maintained their traversal of the Restriction Requirement of April 26, 2006 and reserve the right to pursue non-elected and cancelled subject matter in continuation, divisional, and/or continuation-in-part applications.

Objection to the Claims

Claims 8, 9, and 34 have been cancelled this objection *moot*.

Reconsideration and withdrawal of the objection is respectfully requested.

35 U.S.C. § 112, second paragraph

Claims 7, 34, and 35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The claims have been cancelled rendering this rejection *moot* because the language in question no longer appears in any pending claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, first paragraph (written description)

Claims 1-3, 6, 7, and 34 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

Applicants respectfully note that claims 2-3, 6, 7, and 34 have been cancelled rendering rejection of these claims *moot*.

Applicants respectfully note that the limitations of claim 35, which were indicated as allowable in the Office Action, have been incorporated into claim 1.

The Office Action alleges that the specification does not provide guidance for practicing the invention because for lack of, "...a teaching of a representative number of alleles of a representative number of genes from a representative number of animals such that one of ordinary skill in the art could envision the entire...genus thereof..." Office Action at 6.

Applicants have amended claim 1 to recite two specific genes, *KIT* and *aMSHR* and have provided polymorphisms which are indicative the breed determinant gene of a coat color gene in a pig. Specification at Examples 16-20. Therefore, Applicants have adequately described in the specification, in the form of the examples, polymorphisms, and testing methods, the method for: (a) differentiating animals and animal products on the basis of breed origin; (b) determining or testing the breed origin of an animal product; or (c) validating an animal product comprising the steps of providing a sample of the animal product and analyzing the allele(s) of one or more breed determinant genes present in the sample.

Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102(b)

Claims 1, 3, 6, 7, and 34 were rejected under 35 U.S.C. § 102(b) as anticipated by Joerg *et al.* (1996) “Red coat color in Holstein cattle is associated with a deletion in the *MSHR* gene.” Mammalian Genome 7: 317-318 (“Joerg”). Applicants respectfully traverse this rejection.

Applicants respectfully note that claims 3, 6, 7, and 34 have been cancelled rendering rejection of these claims *moot*.

Applicants respectfully note that the limitations of claim 35, which were indicated as allowable in the Office Action, have been incorporated into claim 1.

Claim 1 is drawn to a method for: (a) differentiating animals and animal products on the basis of breed origin; (b) determining or testing the breed origin of an animal product; or (c) validating an animal product comprising the steps of providing a sample of the animal product and analyzing the allele(s) of one or more breed determinant genes present in the sample, wherein said animal is a pig and said breed determinant gene is KIT or α MSHR.

Since “[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” Electro Med. Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994), Applicants respectfully submit that Joerg fails to meet the limitation of the instant claims because Joerg is drawn to a, “...test for identifying carriers of the recessive red allele among black Holstein cattle.” Joerg at 318. Further, Joerg is silent on differentiating animals and animal products on the basis of breed origin; determining or testing the breed origin of an animal product; or validating an animal product. Nor Joerg does not teach a method comprising testing pig nucleic acids for polymorphisms. Therefore Joerg does not teach that the method of claim 1.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, and 6 were rejected under 35 U.S.C. § 102(b) as anticipated by McPherron *et al.* (May 1, 1997) “Regulation of skeletal muscle mass in mice by a new TGF- β superfamily member.” Nature 387: 83-90 (“McPherron”). Applicants respectfully traverse this rejection.

Applicants respectfully note that claims 2 and 6 have been cancelled rendering rejection of these claims *moot*.

Applicants respectfully note that the limitations of claim 35, which were indicated as allowable in the Office Action, have been incorporated into claim 1.

As discussed above, “[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” Electro Med. Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994). Applicants respectfully submit that McPherron fails to meet the limitation of the instant claims because McPherron is drawn to a study of the biological function of growth/differentiation factor-8 (GDF-8) in mice. McPherron at 83. Further, McPherron is silent on differentiating animals and animal products on the basis of breed origin; determining or testing the breed origin of an animal product; or validating an animal product. Nor McPherron does not teach a method comprising testing pig nucleic acids for polymorphisms. Therefore McPherron does not teach that the method of claim 1.

Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103(a)

Claim 10 was rejected as unpatentable under 35 U.S.C. § 103(a) over Joerg in view of WO 97/05278 (February 13, 1997) Andersson *et al.* (“Andersson”) Applicants respectfully traverse this rejection.

Applicants respectfully note that the limitations of claim 35, which were indicated as allowable in the Office Action, have been incorporated into claim 10.

A proper obviousness rejection of patent application claims under 35 U.S.C. § 103(a) requires a showing by the USPTO that the invention defined in the rejected claim(s) as a whole is obvious in view of one reference or a combination of the references. M.P.E.P. § 2142. Three basic criteria must be met to support a *prima facie* case of obviousness: (a) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference(s) teachings; (b) there must be a reasonable expectation of success; and (c) the prior art reference (or references when combined) must teach or suggest all the claim features. M.P.E.P. § 2143. Here, the references cited in the Office Action do not individually or in combination suggest to a person of ordinary skill in the art the invention of claim 10.

As discussed above, Applicants respectfully submit that Joerg fails to teach all limitations of the instant claim because Joerg is drawn to a, “...test for identifying carriers of the recessive red allele among black Holstein cattle.” Joerg at 318. Further, Joerg is silent on differentiating

animals and animal products on the basis of breed origin; determining or testing the breed origin of an animal product; or validating an animal product. Nor Joerg does not teach a method comprising testing pig nucleic acids for polymorphisms. Therefore Joerg does not teach the method of claim 10.

However, to fill this gap, the Office Action asserts that Andersson discloses that, “[c]oat color is important to the pig breeding industry,” and therefore it would have been obvious to combine the teachings of Joerg with Andersson. Office Action at 10-11. However, the Office Action failed to provide a suggestion or motivation to combine the references. And, as discussed above, Joerg nor Andersson discloses the limitations of claim 35 which have been incorporated into claim 10. Id. at 11.

Applicants submit that the references cited in the Office Action do not individually or in combination suggest to a person of ordinary skill in the art the invention of the Applicants’ claim 10. The Office Action does not present a valid reasonable expectation of success but merely restates the alleged teachings of Joerg with Andersson. See MPEP § 2143.02. Therefore the Office Action does not offer sufficient motivation to combine Joerg with Andersson. Finally, even if, *arguendo*, it were proper to combine the references, it has not been established in the Office Action that the combination would have yielded a method that meets each and every limitation of the claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that claims 1 and 10 are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any issues remain after consideration of this Response, the Examiner is invited to contact the Applicants' undersigned representative to discuss and resolve such issues.

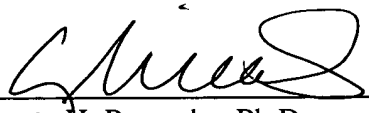
In the event that a variance exists between the amount tendered and that deemed necessary by the U.S. Patent and Trademark Office to enter and consider this Response or to maintain the present application pending, please credit or charge such variance to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

HUNTON AND WILLIAMS, LLP

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